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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/798,119

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Yih-Lin Chung

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04/14/2009

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EXAMINER

HUGHES, ALICIA R

ART UNIT

PAPER NUMBER

1614

NOTIFICATION DATE

DELIVERY MODE

04/14/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

INFO@ORTPATENT.COM

Office Action Summary	Application No. 10/798,119	Applicant(s) CHUNG, YIH-LIN	
	Examiner ALICIA R. HUGHES	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-21 is/are pending in the application.
- 4a) Of the above claim(s) 2-4, 6-10, 12, 13, and 18-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1, 11 and 14-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims and Examination

This Office's Advisory Action of 29 December 2008 is hereby vacated and the finality of the Office Action issued on 09 September 2009 is hereby withdrawn. Claims 1-4 and 6-21 are pending currently. However, only claims 1, 11, and 14-17 are the subject of this Office Action, as claims 2-4, 6-10, 12, 13, and 18-21 are withdrawn from consideration, being drawn to a non-elected invention. See 37 C.F.R. 1.142(b).

Applicant's arguments and amendments filed on 11 June 2008 in response to the Non-Final Rejection filed by this Office on 08 April 2008 is under consideration herein. Rejections and objections not reiterated from previous office actions are hereby withdrawn. The below constitutes all rejections pending.

Claim Rejections – 35 U.S.C. §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 11, and 14-16 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,877,213 [hereinafter referred to as "Samid"].¹

This Office's arguments from its actions of 23 March 2007, 01 October 2007, and 08 April 2008 are incorporated herein by reference in their entirety.

¹ Cited on PTO Form 892 filed on 23 March 2007.

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The Applicant's argument that Samid does not establish a *prima facie* case of obviousness, because the present invention is distinguishable due to its focus on promoting cell proliferation and survival rather than promoting cell death has been considered. However, it is not deemed persuasive for the reasons of record set forth in this Office's previous actions mentioned *supra*. Applicant now argues, additionally, that Samid is an inapplicable reference, because of the patient population the hyperacetylating agent is to treat. Applicants argue that Samid treats patients with anemia, cancer, AIDs or severe β -chain hemoglobinopathies rather than those patients suffering from chemotherapy or radiotherapy induced side effects. Therefore, it is not applicable as prior art in the instant case.

As noted previously, claims are to be given their broadest reasonable interpretation and the claims as written in this application, apply for increasing therapeutic gain associated with tumorigenesis where a patient undergoes radiotherapy or chemotherapy. Tumorigenesis has a direct correlation to malignancy and/or nonmalignant dense structures.

By Applicants' own admission, "the claimed method targets subjects (e.g., cancer patients) who suffer from certain side effects" (Page 9 of Applicants' Remarks). Thus, the patient population in Samid et al and in the instant case may be construed as one in the same. Further, the claims are directed to a "subject in need" and this particular population of need is the population of cancer patients.

In light of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art to administer sodium phenylbutyrate in the manner prescribed by Samid, in combination with radiotherapy, as a method of treating tumorigenesis.

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Claims 1 and 17 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,877,213 [hereinafter referred to as “Samid”] in view of Shufeng, Z., et al., *5,6-Dimethylxanthenone-4-acetic acid (DMXAA): A New Biological Response Modifier for Cancer Therapy*, Investigational New Drugs, vol. 20, 2002, pages 281-295 [hereinafter referred to as “Shufeng, et al.”].²

The teachings of Samid, taught in this Office’s actions of 23 March 2007 and 01 October 2007 are incorporated herein by reference as are the teachings of Shufeng et al from this Office’s action of 01 October 2007 as well as the arguments, *supra*, regarding the applicability of the Samid reference to the instant set of claims.

One of ordinary skill in the art would be motivated to combine the teachings of Samid with the teachings of Shufeng et al., because the references teach overlapping subject matter, most notably, the administration of anti-tumor agents.

In light of the foregoing, one of ordinary skill in the art would be motivated to apply the teachings of Samid and the teachings of Shufeng et al to the present invention, because DMXAA is an anti-cancer agent/biological response modifier that when combined with radiotherapy and/or phenylacetic acid and its pharmaceutically acceptable salts and derivatives, including sodium phenylbutyrate, effectively treats various cancers. When used together, in light of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art that the proliferation of cancers and their associated tumors would be treatable through the combination therapy of sodium phenylbutyrate and DMXAA with radiotherapy.

² Cited on PTO Form 892 filed on 23 March 2007.

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Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see <http://pair-direct-uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alicia R. Hughes/
Examiner, Art Unit 1614

/Kevin E. Weddington/
Primary Examiner, Art Unit 1614